

Message Text

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PAGE 01 STATE 103521

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DRAFTED BY:OES/SCI/BMP:MBEAUBIEN

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EA/J:CDUNKERLEY(VDRAFT)

HEW/FDA:RWEINROTH(DRAFT)

HEW/OIH:JKING(DRAFT)

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R 022348Z MAY 75

FM SECSTATE WASHDC

TO AMEMBASSY TOKYO

UNCLAS STATE 103521

C O R R E C T E D C O P Y (LINE 2, PARA 2)

E.O. 11652: N/A ; ;

TAGS: BIO, JA

SUBJECT: MARUYAMA CANCER VACCINE

REF: A. TOKYO 5374 B. STATE 54740

FOR SCIENCE COUNSELOR

1. SINCE STATEMENT BY FDA CONCERNING POLICY RE MARUYAMA CANCER VACCINE IMPORTATION CONVEYED REF B, NINE INVESTIGATIONAL NEW DRUG (IND) APPLICATIONS HAVE BEEN FILED BY U.S. PHYSICIANS WITH FDA AND APPROVED. THEREFORE IMPORTATION FOR HUMAN USE PERMITTED ONLY BY INVESTIGATORS WHO HAVE BEEN GRANTED IND APPROVALS. ARRANGEMENTS FOR IMPORTATION IS RESPONSIBILITY OF INVESTIGATORS DIRECTLY WITH VACCINE SOURCE AND EMBASSY SHOULD CONTINUE TO AVOID BEING INTERMEDIARY.

2. EMBASSY SHOULD RESPOND TO ANY QUERY TO EFFECT THAT PATIENT'S PHYSICIAN REPEAT PHYSICIAN MAY CONTACT FDA FOR INFORMATION CONCERNING APPROVED INVESTIGATORS IN U.S.

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ADDRESS FOR INQUIRIES: INVESTIGATIONAL NEW DRUG STAFF,

FDA/BUREAU OF BIOLOGICS, BLDG. N25, BETHESDA, MARYLAND
20014, PHONE 301-496-4343. FYI CURRENT USE IS LIMITED
TO TERMINAL CASES WHERE OTHER FORMS OF THERAPY HAVE
FAILED. END FYI.

3. TO ASSIST CONTROL AND MONITORING OF USAGE OF VACCINE
IN U.S., FDA IS IN NEED OF DETAILED INFORMATION ON
MANUFACTURING, INCLUDING CONTROLS AND PROCESS. LOT
NUMBERS MUST BE ASSIGNED AND SHOWN ON VIALS AND
SHIPMENTS. ALSO LABELS MUST HAVE CAUTIONARY STATEMENT
"CAUTION: NEW DRUG-LIMITED BY FEDERAL(OR UNITED STATES)
LAW TO INVESTIGATIONAL USE."

4. DHEW/NCI HAS OBTAINED COPY OF A FORM LETTER FROM
PROF. MARUYAMA TO AN AMERICAN CITIZEN WHICH STATES THAT
"IF YOU WISH TO RECEIVE MY THERAPY, YOU MAY PLEASE SEND
ME THE WRITTEN CONSENT BY YOUR HOME DOCTOR IN CHARGE
FOR THE THERAPY AND THE RECORD OF YOUR PRESENT ILLNESS.
YOUR EMBASSY USUALLY TAKES THE COURTESY TO SEND THE
VACCINES TO YOU FOR YOUR CONVENIENCE. THEREFORE, USUALLY
ON THE REQUEST THROUGH THE EMBASSY, I DELIVER THE
VACCINES TO THE EMBASSY FOR THE TRANSMITTANCE TO YOU."

5. ACTION REQUESTED: PLEASE ADVISE DR. MARUYAMA OF STATUS,
REQUIREMENTS AND INFORMATION NEEDED BY FDA CITED PARAS
1, 2, AND 3 IN ORDER COMPLY WITH U.S. LAW FOR IMPORTATION
HERE. AT SAME TIME NECESSARY THAT DR. MARUYAMA NOT USE
MISLEADING LETTER CITED PARA 4. EMBASSY SHOULD ALSO
INFORM MOHW OF U.S. STATUS OF VACCINE MATTER. KISSINGER

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